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Certificate of Need: Process Appears Clear, Consistent and Transparent, 2011

Maine State Legislature

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OPEGA

Information Brief

Purpose

In March 2011, the Government Oversight Committee asked OPEGA to initiate a limited review of the Certificate of Need (CON) Program. The focus was on the process used, and factors considered, in making determinations on CON applications.

OPEGA reviewed the CON statute and related rules, the annual reports produced on the CON program, and the procedures used by the DHHS Certificate of Need Unit in processing CON applications. OPEGA also reviewed a sample of files for CON applications processed in 2008 – 2010 to assess consistency and adherence to the Certification of Need statutory purpose in making CON determinations.

This Information Brief describes the purpose of the CON program, the processes followed and factors considered in assessing CON applications. OPEGA's limited review found there to be clarity, consistency and transparency in the process as prescribed in the existing statute. Consequently, OPEGA does not recommend any further detailed review of the process itself at this time.

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Certificate of Need: Process Appears Clear, Consistent and Transparent



Summary

Maine's Certificate of Need Act of 2002 (22 MRSA §326-350-C) has its historical base in the 1974 federal "Health Planning Resources Development Act". The federal law required all 50 states to have a process for state-level review and approval of proposals from health care organizations before they began any major capital projects such as building expansions or ordering new high-technology devices. The goal was to restrain health care facility costs and allow coordinated planning of new services and construction.

Many states implemented Certificate of Need (CON) programs to become eligible to receive CON federal funds. The federal mandate was repealed in 1987, along with its federal funding. According to data from the National Conference of State Legislatures, 14 states have since discontinued their CON programs. However, 36 states currently maintain some form of CON program, and even the 14 that repealed their state CON laws still retain some mechanisms intended to regulate costs and duplication of services.

In 22 MRSA §327 the Legislature finds that unnecessary construction or modification of health care facilities, and duplication of health services, are substantial factors in the cost of health care and the ability of the public to obtain necessary medical services. Statute describes the specific purposes of the CON program as:

- supporting effective health planning;
- supporting the provision of quality health care in a manner that ensures access to cost-effective services;
- supporting reasonable choice in health care services while avoiding excessive duplication;
- ensuring that State funds are used prudently in the provision of health care services;
- ensuring public participation in the process of determining the array, distribution, quantity, quality and cost of these health care services;
- improving the availability of health care services throughout the State;
- supporting the development and availability of health care services regardless of the consumer's ability to pay;
- seeking a balance, to the extent a balance assists in achieving the purposes of this law, between competition and regulation in the provision of health care; and
- promoting the development of primary and secondary preventive health services.

To accomplish these purposes, statute requires State approval of certain initiatives proposed by health care and nursing facilities through a defined Certificate of Need process. Those initiatives include the expansion of plant and equipment, the provision of new services, and transfers of ownership and control. The CON process and requirements are further defined in Rules established by the Department of Health and Human Services (DHHS).

The CON Act establishes a number of dollar thresholds that trigger a required review. The thresholds currently in effect are shown in Table 1.

Health care and nursing facilities submit applications seeking a Certificate of Need to the Certificate of Need Unit (CONU) within the DHHS's Division of Licensing and Regulatory Services (DLRS). The CONU staff consists of a Manager, three Health Care Financial Analysts, and administrative support. The Unit is responsible for processing CON applications, analyzing the information provided, and assessing the impacts of the proposed initiatives. CONU ultimately prepares a briefing memo for the Commissioner of the Department of Health and Human Services that summarizes the staff's analysis and recommendations. The Commissioner makes the final determination on whether to approve the application and grant a Certificate of Need.

Table 1. Thresholds Triggering CON Review

Category	Amount
Major Medical Equipment	\$1,600,000
Replacement of Major Medical Equipment	\$2,000,000
Capital Expenditures	\$3,100,000
New Technology	\$1,600,000
Nursing Facility Capital Expenditures	\$718,958
New Health Service	
Capital Expenditure	\$140,098
3rd Year Incremental Operating Costs	\$509,449

Source: Certificate of Need 2010 Annual Report

OPEGA's limited review found that, overall, Maine's Certificate of Need application review and determination process is clear, systematic and transparent. The CONU consistently follows the prescribed process and considers each aspect of an application for approval separately. The Commissioner's determinations appear to be consistent with the staff's recommendations and most approved applications contain conditions intended to assure the initiative complies with the purposes of the Certificate of Need program. More detailed description of the CON process, the particular factors considered in making CON determinations, and the results of OPEGA's review of CON application files is provided in the remainder of this Information Brief.

Nationally, Certificate of Need remains a controversial topic. Supporters contend that CON programs limit health-care spending and promote appropriate competition, while maintaining lower costs for treatment services. Critics say it is not clear CON programs actually control health care costs, while stifling investment in health care. Determining the extent to which Maine's Certificate of Need program is successful in controlling the cost of health care and the ability of the public to obtain necessary medical services would require a much more in depth examination than was within the scope of this limited review.

Certificate of Need Process

Regulated facilities intending to initiate a project that may require a Certificate of Need submit a Letter of Intent describing the project and its anticipated costs to the CONU. The CONU reviews the Letter of Intent and issues a response letter. If the project is of a type that requires a CON and exceeds the threshold amount, the applicant is advised that a Certificate of Need is required. The response letter also stipulates and clarifies what will be required in the application and specifies the applicable review cycle for the application. A "not subject to review" determination is issued if the total projected costs fall below the applicable thresholds or if the nature of the project itself does not require a CON. A "not subject to review" determination is only made once the CONU is satisfied that it has determined all applicable terms and costs of the project.

The CON application approval process is outlined in Figure 1. The CONU staff assist applicants with the process through informal consultation prior to the submission of Letters of Intent, and technical assistance meetings to discuss application requirements prior to submission of the application. To distribute the work throughout the year, the CONU processes Letters of Intent and applications for different types of projects on staggered timelines. Associated deadlines for submission of Letters of Intent and applications are established in the Rules.

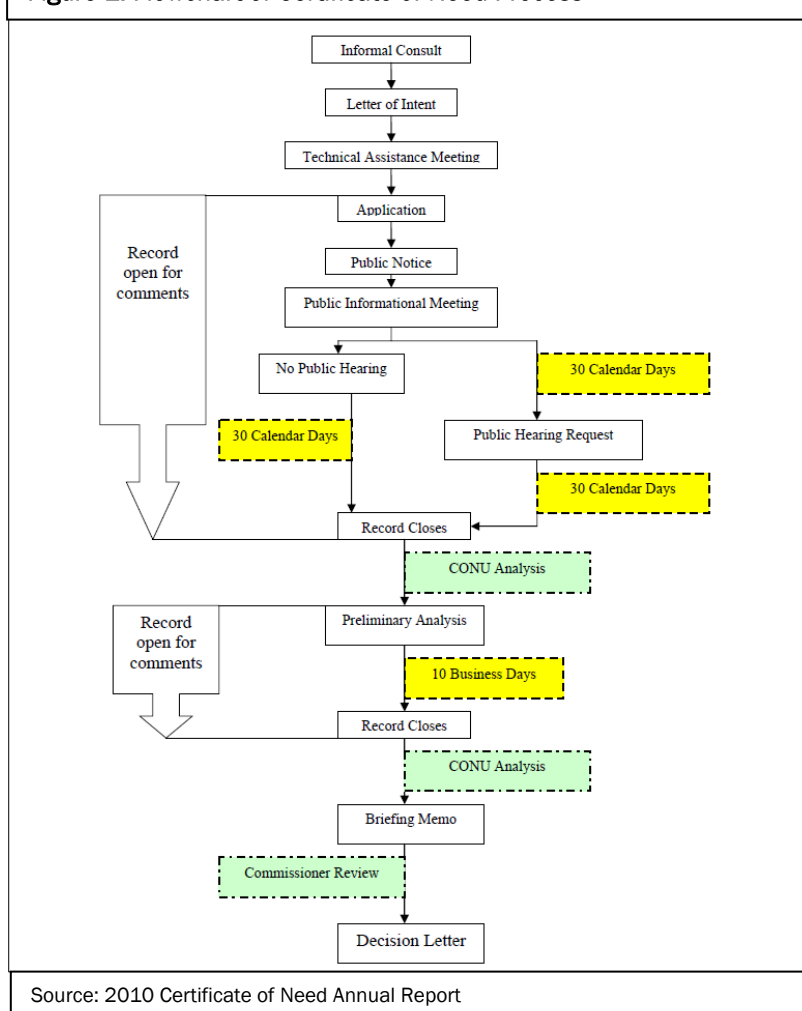
After the CON application is submitted, a public informational meeting is scheduled and a public notice of the meeting is published. The public information meeting is the forum for applicants to present the project details of the CON to the public. The DHHS Commissioner may hold a public hearing where the public has the opportunity to present testimony about the project. Statute also requires a public hearing be held if at least five persons residing within the area to be served by the proposed project submit a written request for one.

The Certificate of Need Unit at DHHS then reviews the CON application, and information and comments from the public. It also takes input from organizations such as the Maine Quality Forum, the Maine Center for Disease Control (CDC) and the Bureau of Insurance. Following its initial analysis, the CONU produces a preliminary analysis report which offers a recommendation on the application. The CONU then opens the record for comments and will accept additional information from the applicant. The CONU considers any additional information and submits a briefing memo, including its final recommendations, to the DHHS Commissioner.

The Commissioner reviews the briefing memo and issues the final decision on the application in a decision letter. Any person directly affected by a final CON decision may request reconsideration of that decision by the Department. Aggrieved persons still not satisfied with the Department's decision may appeal to Superior Court.

From 2008 – 2010, the CONU received and processed 29 CON applications. It also received another 63 Letters of Intent on initiative that CONU determined were “not subject to review”. The CONU explained that facilities planning any kind of project that may be of a type requiring a CON prefer to get a determination from the CONU to have in their files in case the project is questioned later. The CONU has the statutory authority to impose fines and other sanctions on facilities that undertake projects requiring a CON without first obtaining a Certificate.

Figure 1. Flowchart of Certificate of Need Process



Factors Considered in CON Determinations

The Certificate of Need Act of 2002 and the CON Rules specify that the following factors be considered in processing a CON application:

- the applicant is fit, willing and able to provide the proposed services at the proper standard of care;
- the economic feasibility of the proposed services;
- there is a public need for the proposed services;
- the proposed services are consistent with the orderly and economic development of health facilities and health resources for the State;
- the proposed services are consistent with the State Health Plan;
- the proposed services ensure high-quality outcomes and do not negatively affect the quality of care delivered by existing service providers;
- the proposed initiative does not result in inappropriate increases in service utilization; and
- the proposed project can be funded within the Capital Investment Fund.

The applicant must provide information addressing each of these factors in the application. The CONU explained that the individual factors are not weighted, rather they are all baseline requirements for the issuance of a CON and are equally important. However, more time is generally spent on the economic feasibility and other more complex sections. CONU solicits comments on the impact of each project on the health of Maine citizens from both the Maine Quality Forum and the Maine Center for Disease Control (CDC). The Maine Quality Forum also determines if the projects constitute a new technology. Similarly, CONU's analyses include comments from the Bureau of Insurance on the impact of each project on statewide and regional health insurance premiums. The preliminary analysis produced by the CONU on any project includes a discussion and determination on each of the application points, as does the briefing memo that CONU ultimately submits to the Commissioner.

The Capital Investment Fund (CIF) factor does not relate to any funding actually being provided to projects, but rather serves as a cap on the amount of investment introduced into the health care system within a particular timeframe. The CONU looks at whether the projected total third year operating costs for all the initiatives proposed within a given timeframe are within the established CIF level. Although the cap could result in some proposed projects not receiving a Certificate of Need, CONU reports that to date the cap has not been a limiting factor in approving any applications.

The final decision to approve a Certificate of Need application is made by the DHHS Commissioner based upon recommendations made by the Certificate of Need Unit. The Commissioner is free to change the recommendation, add or remove any conditions, and approve or not approve the application. The DHHS Commissioner then produces a final decision letter detailing the decision and any conditions imposed on the project. Any conditions imposed must relate to the established criteria considered in approving the application. OPEGA noted that 22 MRSA §335.2 states that only a person who is a full-time employee of the department with responsibilities for the Certificate of Need program, a consultant to the project or a policy expert pursuant to section 338 of the statute may communicate with the Commissioner regarding any application for a Certificate of Need or any Letter of Intent.

Results of OPEGA File Review

OPEGA reviewed the CONU files for 13 of the CON applications received in the three year period 2008 - 2010. The sample included large projects, small projects, and nursing home facilities, and involved such projects as installation of new equipment, extensive hospital renovations, ownership changes, and the construction of a new regional hospital. The 13 processed application files were reviewed for compliance with statutory timelines, completion of required steps in the process and consideration of all required factors in the decision making process. We found that the Certificate of Need application process is quite structured and consistently followed within each category of project type. The CONU considered each section of the applications separately, and performed analysis and made recommendations on each section in a way that would support thorough and accurate assessments.

OPEGA compared the factors considered in approving an application to the statutory purpose of the CON program, and found that nearly all of the purposes are addressed by one or more of the factors used to make the final determination. The exception is the fifth listed purpose to "ensure public participation in the process of determining the array, distribution, quantity, quality and cost of these health care services". This purpose is satisfied in the CON process by publishing legal notices of, and holding, informational meetings and public hearings when required.

We also reviewed the files for nine of the 63 projects CONU had determined were "not subject to review". Eight of the nine were determined to be below the dollar threshold for review at the time of the proposal. The determination letter for each of them stated if project costs end up exceeding thresholds the applicant will be required to file a CON application. Determinations for five of the eight also mentioned that the proposal "was not a new health service" for the applicant. The remaining proposal of the nine was found to be exempt from the CON process.

Of the 29 CON applications filed in the three year period, 27 were approved, and over the last five years 57 of 60 CON applications were approved. While a high percentage of CON applications have been approved, the CONU points out that most, if not all, of those approvals involved changes to the original proposal and conditions on the approved Certificates. OPEGA observed that conditions imposed include: certain reporting requirements, including reports on client utilization and cost savings or increases; incorporation of green technologies during construction; changes in the size and scope of the project; and a plan to increase patient privacy.